

Wisconsin Department of Regulation & Licensing

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PHARMACY EXAMINING BOARD

BUSINESS MODELS AND THE REQUIREMENTS FOR LICENSURE

(PHARMACY, PRESCRIPTION DRUG DISTRIBUTOR AND DRUG MANUFACTURER)

Drug Manufacturers:

1. Drug or device manufacturing facilities which are located within the state of Wisconsin are required to obtain a manufacturer's license from the board. If the Wisconsin facility also directly distributes these pharmaceuticals at wholesale a distributor's license is also required.
2. A corporate headquarters for a drug manufacturer, located in this state, does not need to be licensed as a manufacturer if the headquarters is not a facility where manufacturing occurs.
3. A drug manufacturer may retain title to prescription drugs distributed to pharmacies until the medications are actually sold to a consumer pursuant to a prescription order. The pharmacy laws in this state do not prohibit the business arrangement proposed.
4. A distributor's license would be required for an out-of-state manufacturing facility if it engages in the wholesale distribution of prescription drugs or devices in this state from that manufacturing facility.
5. Any other distribution facility located in-state or out-of-state, whether or not owned by the manufacturer, must be licensed as a distributor if it engages in the wholesale distribution of prescription drugs or devices in this state.
6. "Wholesale distribution" means distribution of prescription drugs or devices to persons other than a consumer or patient but does not include intracompany sales, which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under the common ownership and control of a corporate entity. This means that a manufacturer can ship prescription drugs and devices from its manufacturing facility (in-state or out-of-state) to a distributor facility (in-state or out-of-state) which are both under common ownership or control without the need for the manufacturing facility to also be licensed as a distributor.

Prescription Drug Distributors:

1. A distributor's license authorizes a facility to sell prescription drugs or devices to pharmacists, pharmacies, researchers, hospitals, authorized agents of the federal government and other distributors. [See, sec. 450.07 (3), Wis. Stats.]. A distributor's license does not authorize a facility to dispense prescription drugs directly to patients pursuant to a prescriber's prescription order. Dispensing directly to patients under a prescription order requires a pharmacy license.
2. Out-of-state or in-state wholesale distributors of prescription drugs are required to obtain a distributor's license in Wisconsin for each facility from which the prescription drugs are distributed.

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3. Distribution by company A of prescription drugs under the label of company B. A distributor's license is required in this state for the facility that distributes a prescription drug into (or in) Wisconsin, irrespective of where that facility is located. The fact that the distributor (company A) may also manufacture the product under a different label does not require a separate manufacturer's license unless the facility is physically located in this state. Nor does Wisconsin law require that the entity whose label is being utilized (here, company B) be licensed as a distributor or manufacturer in this state.
4. Company A recently acquired ownership of certain prescription and OTC products previously distributed by company B along with the right to the use company B's name. The products, themselves, will continue to be distributed from facilities which are currently licensed as wholesale distributors in this state. Company A does not own or operate any of the licensed distributor facilities. Company A is not required to obtain a wholesale distributor's license from this state. A distributor's license is required in Wisconsin for each facility which distributes prescription drugs at wholesale. Although the ownership of the prescription medications being distributed at wholesale has changed, the owner of the licensed distributor facilities has not. Mere "ownership" of prescription drugs or devices being distributed does not require a distributor's license.
5. "Wholesale distribution" means distribution of prescription drugs or devices to persons other than a consumer or patient but does not include intracompany sales, which include any transaction or transfer between any division, subsidiary, parent, affiliated or related company under the common ownership and control of a corporate entity.

Out-of-State Pharmacies:

1. This state does not require a Wisconsin pharmacy license be obtained by pharmacies licensed in another state which dispense prescription medications, including schedule II controlled substances, by mail or other delivery to patients in this state. Wisconsin does not license out-of-state pharmacies at this time.